ENDOLOGIX INC /DE/

FORM 10-K
(Annual Report)

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Powerlink Infrarenal Bifurcated Systems. The Powerlink Infrarenal Bifurcated System is available in multiple diameters and lengths and can treat patients that have an aortic neck up to 32 millimeters in diameter. The infrarenal device is made of a cobalt chromium alloy stent covered by high density ePTFE for placement below the renal arteries. The self-expanding stent permits the graft to be used in a wide range of neck diameters, which allows us to treat a wide variety of anatomies with a standard device. We obtained the CE Mark for this product in Europe in August 1999, and obtained United States Food and Drug Administration, or FDA, pre-marketing approval in October 2004. We commenced commercial sales in the United States in December 2004 and executed a focused United States launch throughout 2005.

Powerlink Aortic Cuffs and Limb Extensions. The Powerlink Proximal Extensions and Limb Extensions permit the physician to treat a greater number of patients. Proximal Extensions are available in 25, 28 and 34 millimeters in diameter and multiple lengths. They also are available in both infrarenal and suprarenal configurations. Limb extensions are available in 16, 20, and 25 millimeters in diameter with various lengths, allowing the physician to customize the technology to treat a wide range of patient anatomies. We have obtained the CE Mark for these products in Europe in October 1999 (16/20 mm Limb Extensions), December 1999 (25/28 mm Proximal Extensions), May 2002 (34 mm Proximal Extensions) and November 2008 (25 mm Limb Extensions). We obtained United States FDA marketing approval in October 2004 (25 and 28 mm proximal infrarenal extensions and the 16 and 20 mm limb extensions), March 2008 (25 mm limb extensions), and October 2008 (34 mm proximal infrarenal and suprarenal extensions and 25 and 28 mm proximal suprarenal extensions). Our large diameter 34mm Proximal Extensions are marketed under the trademark Powerlink XL.

IntuiTrak. In October 2008, we received FDA approval for a new system to deliver and deploy the Powerlink stent graft. The new system, called IntuiTrak, was designed to further simplify the implant procedure and provide a delivery profile advantage over many competitive devices. It is expected to be available for full market introduction in the second quarter of 2009.

Clinical Trials

Powerlink Systems

We continue to conduct clinical trials for other products related to the Powerlink System. As of December 31, 2008, all the required 63 patients have been enrolled in a clinical trial for a 34mm infrarenal bifurcated device designed to treat patients with large aortic necks.

Marketing and Sales

Powerlink System

United States. We began a focused launch of the Powerlink System in the United States with six sales representatives and two clinical specialists in late 2004. We have expanded our domestic sales force to 52 defined sales territories. As of December 31, 2008, 46 of these territories were filled. The primary customer and decision maker for these devices in the United States is the vascular surgeon. Through our direct sales force, we provide clinical support and service to many of the approximately 1,600 hospitals in the United States who perform endovascular aneurysm repair.

Europe. The market for ELGs in Europe is influenced by vascular surgeons, interventional radiologists and, to a lesser extent, interventional cardiologists who perform catheter directed treatment of AAA. The European market is less concentrated than the domestic market. We have obtained the right to affix the CE Mark to our family of Powerlink products. Europe represents a smaller market opportunity due to capitated hospital budgets and a selling price that is typically less than in the United States. We currently sell our devices through exclusive independent distributors.

Japan. The Powerlink System received Shonin approval, which is equivalent to FDA approval of a PMA application in the United States, in February 2008. We commenced commercial sales to Japan in February 2008 through Cosmotec our exclusive distributor in that country.

Dividend Policy

We have never paid any dividends. We currently intend to retain all earnings, if any, for use in the expansion of our business and therefore do not anticipate paying any dividends in the foreseeable future. Additionally, the terms of our credit facility with Silicon Valley Bank, which was entered into on February 21, 2007 and amended on July 22, 2008, prohibit us from paying cash dividends without their consent.

Item 6. ***Selected Financial Data***

The following selected consolidated financial data has been derived from our audited consolidated financial statements. The audited consolidated financial statements for the fiscal years ended December 31, 2008, 2007, and 2006 are included elsewhere in this Annual Report on Form 10-K. The information set forth below should be read in conjunction with Management's Discussion and Analysis of Financial Condition and Results of Operations and consolidated financial statements and notes thereto included herein.

	Year Ended December 31,				
	2008	2007	2006	2005	2004
	(In thousands, except per share data)				
Consolidated Statement of Operations Data:					
Revenue:					
Product	$ 37,631	$ 27,017	$ 14,422	$ 6,889	$ 3,019
License	33	754	250	250	1,213
Total revenue	37,664	27,771	14,672	7,139	4,232
Cost of sales:					
Cost of product sales	10,380	10,539	6,330	3,859	1,851
Total cost of sales	10,380	10,539	6,330	3,859	1,851
Gross profit	27,284	17,232	8,342	3,280	2,381
Operating costs and expenses:					
Research and development	6,060	6,372	6,765	5,817	6,159
Marketing and sales	23,794	20,142	14,579	8,794	2,718
General and administrative	9,477	6,380	5,585	4,801	3,548
Termination of supply agreement	—	550	—	—	—
Minority interest	—	—	—	—	—
Total operating costs and expenses	39,331	33,444	26,929	19,412	12,425
Loss from operations	(12,047)	(16,212)	(18,587)	(16,132)	(10,044)
Total other income	55	1,137	1,044	614	361
Net loss	$(11,992)	$(15,075)	$(17,543)	$(15,518)	$ (9,683)
Basic and diluted net loss per share	$ (0.28)	$ (0.35)	$ (0.44)	$ (0.46)	$ (0.31)
Shares used in computing basic and diluted net loss per share	43,045	42,796	40,010	33,951	31,149

	December 31,				
	2008	2007	2006	2005	2004
			(In thousands)		
Consolidated Balance Sheet Data:					
Cash, restricted cash and cash equivalents	$ 8,111	$ 9,228	$ 6,771	$ 8,691	$ 4,831
Marketable securities available-for-sale	—	—	13,417	8,959	17,085
Working capital	15,876	18,365	26,933	22,520	23,477
Total assets	37,263	40,043	52,686	47,944	44,512
Accumulated deficit	(143,730)	(131,738)	(116,663)	(99,120)	(83,602)
Total stockholders' equity	25,817	34,675	46,505	42,207	41,551

Item 7. ***Management's Discussion and Analysis of Financial Condition and Results of Operations***

The following discussion and analysis should be read in conjunction with "Selected Financial Data" and our consolidated financial statements and the related notes included in this Annual Report on Form 10-K. This discussion contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those anticipated in the forward-looking statements as a result of various factors including the risks we discuss in Item 1A of Part I, "Risk Factors" and elsewhere in this Annual Report on Form 10-K.

Overview

Our Business

We are engaged in the development, manufacturing, marketing and sale of minimally invasive treatments for aortic disorders. Our primary focus is the marketing and sale of the Powerlink System, a catheter-based alternative treatment to surgery for AAA. AAA is a weakening of the wall of the aorta, the largest artery of the body. Once AAA develops, it continues to enlarge and if left untreated becomes increasingly susceptible to rupture. The overall patient mortality rate for ruptured abdominal aortic aneurysms is approximately 75%, making it a leading cause of death in the United States.

Prior to the acquisition of former Endologix and the restructuring that occurred during the third and fourth quarters of 2001, we were researching, developing and marketing a radiation therapy catheter for the treatment of blockages in arteries after angioplasty, or restenosis.

Between 1999 and 2003, our source of revenues shifted gradually from direct sales of previous catheter and stent products to royalties from licenses of our stent delivery technology. In June 1998, we licensed to Guidant rights to manufacture and distribute products using our Focus technology for the delivery of stents in exchange for milestone and royalty payments. In April 2006, Abbott acquired Guidant's vascular business, including all rights and obligations under the license.

Our license revenue decreased in 2008 from 2007. In 2007, under our licensing agreement with BioLucent, Inc., we received $504,000 in royalties and fees, including a one-time payment of $500,000 in exchange for a fully paid-up license to certain of our patents. License revenue from Abbott remained at the contractual minimum level of $250,000 for 2007 and the minimum payment requirement under the agreement expired at December 31, 2007. In 2008, we received de minimus royalties under this agreement prior to its expiration in June 2008. Sales of our Powerlink System are now our only material source of revenue.

For the years ended December 31, 2008 and 2007, we incurred net losses of $12.0 million and $15.1 million, respectively. As of December 31, 2008, we had an accumulated deficit of approximately $143.7 million.

We believe that our current cash balance, in combination with cash receipts generated from sales of the Powerlink System and borrowings available under our credit facility, will be sufficient to fund ongoing operations through at least December 31, 2009. If we do not realize expected revenue and gross margin levels, or if we are unable to manage our operating expenses in line with our revenues, or if we cannot maintain our days sales outstanding accounts receivable ratio, we may not be able to fund our operations through December 31, 2009.

In the event that we require additional funding to continue our operations, we will attempt to raise the required capital through either debt or equity arrangements. We cannot provide any assurance that the required capital would be available on acceptable terms, if at all, or that any financing activity would not be dilutive to our current stockholders. If we are not able to raise additional funds, we may be required to significantly curtail our operations and this would have an adverse effect on our financial position, results of operations and cash flows.

Summary of Accounting Policies and Use of Estimates

The preparation of financial statements in conformity with generally accepted accounting principles requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, revenues and expenses, and related disclosure of contingent assets and liabilities. On an on-going basis, we evaluate our estimates, including those related to collectibility of customer accounts, whether the cost of inventories can be recovered, the value assigned to and estimated useful life of intangible assets, the realization of tax assets and estimates of tax liabilities, contingent liabilities and the potential outcome of litigation. We base our estimates on historical experience and on various other assumptions that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities. Actual results may differ from these estimates under different assumptions or conditions.